

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. et No.

60807-A-PCT-US

Serial No.

09/816,989

Applicants

Alexander Gad and Dora Lis

Filing Date

March 23, 2001

Group Art Unit

1644

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	US 5 5 5 4 3 7 2	9/10/96	Hunter et al.			
	US 5 5 8 3 0 3 1	12/10/96	Stern			
	US 5 6 2 3 0 5 2	4/22/97	McLean et al.			
	US 5 7 3 4 0 2 3	3/31/98	Bishwajit et al.			
	US 5 8 8 6 1 5 6	3/23/99	McLean et al.			
	US 09 4 8 7 7 9 3	1/20/00				
	US 09 6 2 0 2 1 6	7/20/02				
	US 09 7 6 5 3 0 1					
	US 09 7 6 5 6 4 4					

RECEIVED

SEP 20 2002

TECH CENTER 1600/2900

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
					Yes No
WO 9 2 0 2 5 4 3	2/20/92	Europe			
WO 9 4 0 3 4 8 4	2/17/94	US			
WO 9 4 2 6 7 7 4	11/24/94	US			
WO 9 5 2 6 9 8 0	10/12/95	US			
WO 9 5 3 1 9 9 7	11/30/95	US			
WO 0 1 5 2 8 7 8	7/26/01	US			
WO 0 1 9 3 8 9 3	12/3/01	US			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Fridkis-Hareli et al., "Synthetic Peptides that Inhibit Binding of the Collagen Type II 261-273 Epitope to Rheumatoid Arthritis-Associated HLA-DR1 and DR4 Molecules and Collagen-Specific T-cell Responses", Database HCAPLUS on STN, Department of Clinical Immunology, Aarhus University Hospital, Aarhus, Denmark, HCAPLUS AN: 2000:455053, Human Immunology, 2000, 61(7): 640-650 (Abstract)
	Henry, Celia M., "Special Delivery", Chem. and Eng. News, Sept. 18, 2000, 49-54
	Cazzato et al., "Treatment of Multiple Sclerosis. The Present and the Future. Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universita, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in Medicina, October 1999, 90(10): 538-544 (Abstract)

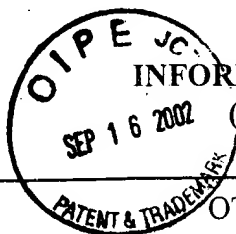
EXAMINER

DATE CONSIDERED

3/8/03

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeApplication No.
60807-A-PCT-USSerial No.
09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad and Dora Lis

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Cohen, "Fundamental Immunology", Systemic Autoimmunity, 4th Ed., 1999, 1083.Fridkis-Hareli et al., "Binding of random copolymers of three amino acids to class II MHC molecules", Intl. Immunol., 1999, 11(5): 635-641Kepsutlu et al., "Evaluation of Chitosan Used as an Excipient in Tablet Formulations", Database HCAPLUS on STN, Department of Pharmaceutical Technology, Gulhane Military Medical Academy, Ankara, 06018, Turkey, HCAPLUS AN: 1999: 590411, Acta. Pol. Pharm. 1999, 56(3): 27-235 (Abstract)Prat et al., "Lymphocyte Migration and Multiple Sclerosis: Relation with Disease Course and Therapy," Ann. Neurol., 1999, 46: 253-256Li et al., "Glatiramer acetate blocks the activation of THP-1 cells interferon- γ ", Eur. J. Pharmacol., 1998, 342:303-310Zisman et al., "Dichotomy between the T and the B cell epitopes of the synthetic polypeptide (T,G)-A--L", Eur. J. Immunol., 1994, 24(10): 2497-2505 (Abstract)Kropshofer et al., "Self-Peptides from Four HLA-DR Alleles Share Hydrophobic Anchor Residues Near the NH₂-Terminal Including Proline as a Stop Signal for Trimming", J. Immunol., 1993, 151: 4732-4742Deeb et al., "Comparision of Freund's and Ribi adjuvants for inducing antibodies to the synthetic antigen (TG)-AL in rabbits", J. Immunol. Methods, 1992, 152(1): 105-113 (Abstract)Zisman et al., "Direct binding of a synthetic multichain polypeptide to Class II Major Histocompatibility Complex molecules on Antigen-Presenting Cells and stimulation of a specific T-cell line require processing of the polypeptide", Proc. Natl. Acad. Sci. USA, 1991, 88(21): 9732-9742 (Abstract)Matsunaga et al., "Complementation of Class II A alleles in the immune response to (Glu-Lys-Tyr) polymers", Yokohama Med. Bull., 1988, 39(1-2): 9-19 (Abstract)De Kruffy et al., "Analysis of T Cell Responses to Poly-L (GluLys) at the Clonal Level. I. Presence of Responsive Clones in Nonresponder Mice", Eur. J. Immunol., 1987, 17 (8): 1115-1120 (Abstract)Lai et al., "Complementation of Class II A alleles in the immune response to (GluLysTyr) polymers", Exp. Clin. Immunogenet., 1986, 3(1): 38-48 (Abstract)Lai et al., "Monoclonal T cell Responses to Two Epitopes on a Single Immunogen Controlled by Two Distinct Genes", J. Immunol., 1986, 136(10):3799-3804 (Abstract)

EXAMINER

DATE CONSIDERED

3/8/03

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

SEP 20 2002

TECH CENTER 1600/2900

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

60807-A-PCT-US

Serial No.

09/816,989



INFORMATION DISCLOSURE CITATION

Use several sheets if necessary)

Applicants

Alexander Gad and Dora Lis

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Trannoy et al., "Epitope-specific regulation of the T cell repertoire: carrier recognition in association with I-E or I-A does not influence the restriction of hapten-specific T cells", Eur. J. Immunol., 1985, 15(12): 1215-1221 (Abstract)

Falo et al., "Analysis of antigen presentation by metabolically inactive accessory cells and their isolated membranes", Proc. Natl. Acad. Sci. USA, 1985, 82(19): 6647-6651 (Abstract)

Babu et al., "Ir gene control of T and B Cell Responses to Determinants in (Glu Lys Ala) Terpolymer", J. Immunogenet., 1984, 11(3-4): 251-254

Babu et al., "Reevaluation of response patterns of nonresponder mice to GLPhe polymers", Immunogen., 1983, 18(1): 97-100 (Abstract)

Herzenberg et al., "Lack of immune response gene control for induction of epitope-specific suppression by TGAL antigen", Nature, 1982, 295: 329-331 (Abstract)

Baxevanis et al., "Genetic Control of T-Cell Proliferative Responses to Poly (Glu⁴⁰Ala⁶⁰) and Poly (Glu⁵¹Lys³⁴Tyr¹⁵): Subregion-Specific Inhibition of the Responses with Monoclonal Ia Antibodies", Immunogenetics, 1980, 11: 617-628

Maurer et al., "Interpretations of immune responses of mice to poly(Glu60Lys40), its modified derivatives, and the terpolymers poly (Glu55Lys37Leu8) and poly (Glu56Lys37Ser7)", Clin. Immunol. Immunopathol., 1980, 15(3): 344-356 (Abstract)

Ju et al., "Idiotypic analysis of antibodies against the terpolymer L-glutamic acid 60-L-alanine30-L-tyrosine10 (GAT). IV. Induction of CGAT idio type following immunization with various synthetic polymers containing glutamic acid and tyrosine", Eur. J. Immunol., 1979, 9(7): 553-560 (Abstract)

Schwartz et al., "Gene complementation in the T lymphocyte proliferative response to poly (Glu57Lys38Tyr5): Evidence for effects of polymer handling and gene dosage", J. Immunol., 1979, 123(1): 272-278 (Abstract)

DATE CONSIDERED

3/8/03

INER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

SEP 20 2002

TECH CENTER 1600/2900

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeApplicant No.
60807-A-PCT-USSerial No.
09/816,989INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)Applicants
Alexander Gad et al.Filing Date
March 23, 2001Group Art Unit
1644

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	US 3 8 4 9 5 5 0	11/19/74	Teitelbaum et al.			
	US 4 3 3 9 4 3 1	7/13/82	Gaffar			
	US 5 2 0 4 0 9 9	4/20/93	Barbier et al.			
	US 5 5 9 1 6 2 9	1/7/97	Rodriguez et al.			
	US 5 6 2 7 2 0 6	5/6/97	Hupe et al.			
	US 5 6 6 8 1 1 7	9/16/97	Shapiro et al.			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No
WO 8 8 1 0 1 2 0	12/29/88	US				
WO 9 5 3 1 9 9 0	11/30/95	US				
WO 9 5 3 3 4 7 5	12/14/95	Europe				
WO 9 8 3 0 2 2 7	7/16/98	US				
WO 0 0 0 5 2 4 9	2/3/00	US				
WO 0 0 0 5 2 5 0	2/3/00	US				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", <u>Eur. J. Immunol.</u> , 1971, 1, 242-248
	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", <u>Israel J. Med. Sci.</u> , 1971, 7, 630-631 (Abstract)
	Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Copolymer Immunological Cross Reactive with Basic Encephalitogen", <u>Israel J. Med. Sci.</u> , 1972, 8, 1759-1760
	Teitelbaum, et al., "Protection Against Experimental Allergic Encephalomyelitis", <u>Nature</u> , 1972, 240, 564-566
	Webb, et al., "Further Studies on the Suppression of Experimental Allergic Encephalomyelitis by Synthetic Copolymer", <u>Israel J. Med. Sci.</u> , 1972, 8, 656-657

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	US 5 7 1 9 2 9 6	2/17/98	Acton III, et al.			
	US 5 8 0 0 8 0 8	9/1/98	Konfino et al.			
	US 5 8 5 8 9 6 4	1/12/99	Aharoni et al.			
	US 5 9 8 1 5 8 9	11/9/99	Konfino et al.			
	US 5 9 5 8 9 7 2	9/28/99	Hupe et al.			
	US 6 0 4 8 8 9 8	4/11/00	Konfino et al.			
	US 6 0 5 4 4 3 0	4/25/00	Konfino et al.			
	US 6 2 1 4 7 9 1	4/10/01	Arnon et al.			
	US 6 3 4 2 4 7 6	1/29/02	Konfino et al.			
	US 2001 00 55 56 8 A1	12/27/01	Gilbert et al.			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No
WO 0 0 1 8 7 9 4	4/6/00	US				
WO 0 0 2 0 0 1 0	4/13/00	US				
WO 0 0 2 7 4 1 7	5/18/00	US				
WO 0 1 6 0 3 9 2	8/23/01	US				
WO 0 1 9 3 8 2 8	12/13/01	US				
WO 0 1 9 7 8 4 6	12/27/01	US				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis with Basic Polymers", <u>Eur. J. Immunol.</u> , 1973, <u>3</u> , 273-279
	Webb, et al., "In Vivo and in Vitro Immunological Cross-reactions between Basic Encephalitogen and Synthetic Basic Polypeptides Capable of Suppressing Experimental Allergic Encephalomyelitis", <u>Eur. J. Immunol.</u> , 1973, <u>3</u> , 279-286
	Teitelbaum, et al., "Dose-response Studies on Experimental Allergic Encephalomyelitis Suppression by COP-1", <u>Israel J. Med. Sci.</u> , 1974, <u>10</u> (9), 1172-1173

EXAMINER

DATE CONSIDERED

3/8/03

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

App. Scket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	US 09 3 5 9 0 9 9	7/22/99	Strominger et al.			
	US 09 4 0 5 7 4 3	9/24/99	Gad et al.			
	US 09 8 1 6 9 8 9	3/23/01	Gad et al.			
	US 09 8 7 5 4 2 9	6/5/01	Yong and Chabot			
	US 09 8 8 5 2 2 7	6/20/01	Rodriguez and Ure			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	EP 0 3 8 3 6 2 0	8/22/90	Europe				
	EP 0 3 5 9 7 8 3	11/29/95	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Clin. Immunol. Immunopath.</u> , 1974, <u>3</u> , 256-262
	Webb, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Isr. J. Med. Sci.</u> , 1975, <u>11</u> , 1388 (Abstract)
	Webb, et al., "Molecular Requirements Involved in Suppression of EAE by Synthetic Basic Copolymers of Amino Acids", <u>Immunochem.</u> , 1976, <u>13</u> , 333-337
	Abramsky, et al., "Effect of a Synthetic Polypeptide (COP-1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis", <u>J. Neurol. Sci.</u> , 1977, <u>31</u> , 433-438
	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Baboons by Cop 1", <u>Israel J. Med. Sci.</u> , 1977, <u>13</u> , 1038 (Abstract)
	Arnon, et al., "Suppression of EAE in Baboons by a Synthetic Polymer of Amino Acids", <u>Neurol.</u> , 1978, <u>28</u> , 336 (Abstract)
	Sela, et al., "Experimental Allergic Encephalomyelitis" in <u>Menarini Series on Immunopathology</u> , vol. 1, First Symposium of <u>Organ Specific Autoimmunity</u> , Cremona, Italy, June, 1977, (Miescher P.A. ed., Schwabe Co., Basel, 1978), 9-21
	Alvord, et al., "Myelin Basic Protein Treatment of Experimental Allergic Encephalomyelitis in Monkeys", <u>Ann. Neurol.</u> , 1979, <u>6</u> , 469-473

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 60807-A-PCT-US	Serial No. 09/816,989
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Applicants Alexander Gad et al.	
		Filing Date March 23, 2001	Group Art Unit 1644
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	Keith, et al., "The Effect of COP 1, a Synthetic Polypeptide, on Chronic Relapsing Experimental Allergic Encephalomyelitis in Guinea Pigs" <u>J. Neurol. Sci.</u> , 1979, <u>42</u> , 267-274		
	Lando, et al., "Effect of Cyclophosphamide on Suppressor Cell Activity in Mice Unresponsive to EAE", <u>J. Immunol.</u> , 1979, <u>123</u> , 2156-2160 (Abstract)		
	Lando et al., "Experimental Allergic Encephalomyelitis in Mice - Suppression and Prevention with COP-1", <u>Israel J. Med. Sci.</u> , 1979, <u>15</u> , 868-896 (Abstract)		
	Teitelbaum, et al., "Blocking of Sensitization to Encephalitogenic Basic Protein in Vitro by Synthetic Basic Copolymer (COP 1)" in <u>Cell Biology and Immunology of Leukocyte Function</u> (Academic Press, New York, 1979) 681-685		
	Teitelbaum, "Suppression of Experimental Allergic Encephalomyelitis with a Synthetic Copolymer - Relevance to Multiple Sclerosis", in <u>Humoral Immunity in Neurological Diseases</u> (Karcher D., Lowenthal A. & Strosberg A.D., eds., Plenum Publishing Corp., 1979) 609-613.		
	Arnon, et al., "Desensitization of Experimental Allergic Encephalomyelitis with Synthetic Peptide Analogues" in <u>The Suppression of Experimental Allergic Encephalomyelitis and Multiple Sclerosis</u> (Academic Press, New York, 1980) 105-107		
	Arnon, "A Synthetic Copolymer of Amino Acids in a Clinical Trial for MS Therapy" in <u>Progress in Multiple Sclerosis Research</u> (Bauer, Ritter, eds., Springer Verlag New York, 1980) 416-418		
	Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", <u>Ann. Neurol.</u> , 1980, <u>8</u> , 117 (Abstract)		
	Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", <u>Trans. Am. Neurol. Assoc.</u> , 1980, <u>105</u> , 348-350		
	McDermott, et al., "Antigen-induced Suppression of Experimental Allergic Neuritis in the Guinea Pig", <u>J. Neurol. Sci.</u> , 1980, <u>46</u> , 137-143		
	Arnon, "Experimental Allergic Encephalomyelitis - Susceptibility and Suppression", <u>Immunological Rev.</u> , 1981, <u>55</u> , 5-30		
	Bornstein et al., "Multiple Sclerosis: Trial of a Synthetic Polypeptide", <u>Ann. Neurol.</u> , 1982, <u>11</u> , 317-319		
EXAMINER <i>PLA</i>	DATE CONSIDERED <i>3/8/83</i>		
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Brosnan, et al., "The Response of Normal Human Lymphocytes to Copolymer 1", J. Neuropath. Exp. Neurol., 1983, 42, 356 (Abstract)

Lisak, et al., "Effect of Treatment with Copolymer 1 (Cop-1) on the in Vivo and in Vitro Manifestations of Experimental Allergic Encephalomyelitis (EAE)", J. Neurol. Sci., 1983, 62, 281-293

Bornstein, et al., "Clinical Trials of Copolymer 1 in Multiple Sclerosis", Ann. N.Y. Acad. Sci. (USA), 1984, 366-372

Bornstein, et al., "Clinical Trials of a Synthetic Polypeptide (Copolymer 1) for the Treatment of Multiple Sclerosis" in Gonsett et al., Immunological and Clinical Aspects of Multiple Sclerosis (MTP Press, The Hague, 1984) 144-150

Brosnan, et al., "Copolymer 1: Effect on Normal Human Lymphocytes", Ann. N.Y. Acad. Sci. (USA), 1984, 436, 498-499

Bornstein, et al., "Multiple Sclerosis: Clinical Trials of a Synthetic Polypeptide, Copolymer 1", Neurol., 1985, 35 (Suppl. 1), 103 (Abstract)

Brosnan, et al., "Immunogenic Potentials of Copolymer 1 in Normal Human Lymphocytes", Neurol., 1985, 35, 1754-1759

Burns, et al., "Human Cellular Immune Response in Vitro to Copolymer 1 and Myelin Basic Protein (MBP)", Neurol., 1985, 35 (Suppl. 1), 170 (Abstract)

Teitelbaum, et al., "Monoclonal Antibodies to Myelin Basic Protein Cross React with Synthetic EAE-suppressive Copolymer, COP 1" in Proc. 7th Eur. Immunol. Mtg., Jerusalem, September 8-13, 1985 (Abstract)

Thompson, "MCQ Tutor: Medical Immunology Multiple Choice Questions", Immunol. Today, 1985, 6(4), 141

Burns, et al., "Human Cellular Immune Response to Copolymer 1 and Myelin Basic Protein", Neurol., 1986, 36, 92-94

Bornstein, "Cop 1 May be Beneficial for Patients with Exacerbating-remitting Form of Multiple Sclerosis", Adv. Ther. (USA), 1987, 4, 206 (Abstract)

Bornstein, et al., "A Pilot Trial of Cop 1 in Exacerbating-remitting Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 408-414

Rolak, "Copolymer-I Therapy for Multiple Sclerosis", Clin. Neuropharmacology, 1987, 10(5), 389-396

Winer, "COP 1 Therapy for Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 442-444

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
60807-A-PCT-USSerial No.
09/816,989INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)Applicants
Alexander Gad et al.Filing Date
March 23, 2001Group Art Unit
1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Arnon, et al., "Suppression of Demyelinating Diseases by Synthetic Copolymers", in A Multidisciplinary Approach to Myelin Disease (G. Serlupi Crescenzi, ed., Plenum Publishing Corp., 1988) 243-250.

Baumhefner, et al., "Copolymer 1 as Therapy for Multiple Sclerosis: The Cons", Neurol., 1988, 38(Suppl. 2), 69-71

Bornstein, et al., "Clinical Experience with COP-1 in Multiple Sclerosis", Neurol., 1988, 38(Suppl. 2), 66-69

Teitelbaum, et al., "Specific Inhibition of the T-cell Response to Myelin Basic Protein by the Synthetic Copolymer Cop 1", Proc. Natl. Acad. Sci. USA, 1988, 85, 9724-9728

Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by Cop-1 - Relevance to Multiple Sclerosis", Israel J. Med. Sci., 1989, 25, 686-689

Bornstein, et al., "Pilot Trial of COP-1 in Chronic Progressive Multiple Sclerosis: Preliminary Report", from The International Multiple Sclerosis Conference: An Update on Multiple Sclerosis, Roma (Italy), September 15-17, 1988, in Elsevier Science Publisher, 1989, 225-232

Teitelbaum, et al., "Clinical Trial of Copolymer 1 in Multiple Sclerosis" J. Israel Med. Assoc., 1989, CXVI(9), 453-456

Bornstein, et al., "Clinical Trials of Cop 1 in Multiple Sclerosis" in Handbook of Multiple Sclerosis (S.D. Cook Marcel Rekker, ed., 1990) 469-480

Carter, et al., "Newer Drug Therapies for Multiple Sclerosis", Drug Therapy, 1990, 31-32, 37-39, 42-43

Grgacic, et al., "Cell-mediated Immune Response to Copolymer 1 in Multiple Sclerosis Measured by the Macrophage Procoagulant Activity Assay", Int. Immunol., 1990, 2(8), 713-718

Kay, et al., "The Mechanism of Action of FK 506", Transplantation Proceedings, 1990, 22(1, Suppl. 1), 96-99

Lee, et al., "Peptide and Protein Drug Delivery" in Advances in Parenteral Sciences (Vincent H.L. Lee, ed., Marcel Dekker, Inc., 1990) 691-695

Myers, et al., "The Peculiar Difficulties of Therapeutic Trials for Multiple Sclerosis", Neurologic Clinics, 1990, 8(1), 119-141

Sela, et al., "Suppressive Activity of COP-1 in EAE and its Relevance to Multiple Sclerosis", Bull. Inst. Pasteur, 1990, 88, 303-314

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

App. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Starzl, <u>Transplantation Proceedings</u> , 1990, 22 (1, Suppl. 1), 5
	Wender, "Copolymer 1 (COP-1) in the Treatment of Multiple Sclerosis (letter)" <u>Neur. Neurochir. Pol.</u> , 1990, 24, 113
	Bornstein, et al., "A Placebo-controlled, Double-blind, Randomized Two-center, Pilot Trial of Cop 1 in Chronic Progressive Multiple Sclerosis", <u>Neurol.</u> , 1991, 41, 533-539
	Burns, et al., "Failure of Copolymer 1 to Inhibit the Human T-cell Response to Myelin Basic Protein", <u>Neurol.</u> , 1991, 41, 1317-1319
	Clinical Trial Protocol No. 9001, Teva Pharmaceutical Industries, Ltd., first patient enrolled October 23, 1991
	Ferrara, et al., "Graft-Versus-Host Disease", <u>New Eng. J. Med.</u> , 1991, 324, 667-674
	Meiner, "COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple-Sclerosis: One Year Follow-up", <u>J. Neurol.</u> , 1991(Suppl. 1) (Abstract)
	Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", <u>Ann. Rev. Immunol.</u> , 1991, 9, 527-565
	Salvetti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", <u>Department of Neurological Sciences, University of Rome, La Sapienza</u> 1991, 72 (Abstract)
	Teitelbaum, et al., "Cross-reactions and Specificities of Monoclonal Antibodies Against Myelin Basic Protein and Against the Synthetic Copolymer 1", <u>Proc. Natl. Acad. Sci. (USA)</u> , 1991, 88, 9528-9532
	Van den Bogaerde, et al., "Induction of Long-Term Survival of Hamster Heart Xenografts in Rats", <u>Transplantation</u> , 1991, 52, 15-20
	Bornstein et al., "Treatment of Multiple Sclerosis with Copolymer 1" in <u>Treatment of Multiple Sclerosis: Trial Design, Results and Future Perspectives</u> (Rudick R.A. & Goodkin D.E., eds., Springer Verlag, London, 1992, 173-198
	Johnson, "Clinical Studies in Copolymer 1 Therapy for Exacerbating-remitting Multiple Sclerosis", in <u>Congress for Advances in the Understanding and Treatment of Multiple Sclerosis</u> , Boston (USA), Oct. 28-29, 1992
	Milo, et al., "Inhibition of Myelin Basic Protein-specific Human T-cell Lines by COP-1", <u>Israel J. Med. Sci.</u> , 1992, 28, 486 (Abstract)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Pat. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Racke, et al., "Copolymer-1-induced Inhibition of Antigen-specific T Cell Activation: Interference with Antigen Presentation", J. Neuroimmunol., 1992, 37, 75-84

Teitelbaum, et al., "Synthetic Copolymer 1 Inhibits Human T-cell Lines Specific for Myelin Basic Protein", Proc. Natl. Acad. Sci. (USA), 1992, 89, 137-141

Weinshenker, et al., "Natural History and Treatment of Multiple Sclerosis", Current Opinion in Neurol. and Neurosurgery, 1992, 5, 203-211

Aharoni, et al., "T Suppressor Hybridomas and Interleukin-2-Dependent Lines Induced by Copolymer 1 or by Spinal Cord Homogenate Down-Regulate Experimental Allergic Encephalomyelitis", Eur. J. Immunol., 1993, 23, 17-25

Arnon, et al., "Immunomodulation of Experimental Allergic Encephalomyelitis", Israel J. Med. Sci., 1993, 29, 175-181

Arnon, et al., "On the Existence of Suppressor Cells", Int. Arch. Allergy Immunol., 1993, 100, 2-7

Clinical Trial Protocol No. 9002, Lemmon Co. and Teva Pharmaceutical Industries, Ltd., first patient enrolled June 17, 1993

Francis, "The Current Therapy of Multiple Sclerosis", J. Clin. Pharmacy and Therapeutics, 1993, 18, 77-84

Keleman, et al., "Graft-versus-Host Disease in Bone Marrow Transplantation: Experimental, Laboratory, and Clinical Contributions of the Last Few Years", Int. Arch. Allergy Immunol., 1993, 102, 309-320

Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", Israel J. Med. Sci., 1993 (Abstract)

Meiner et al., "The Israeli COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple Sclerosis - Two year Follow-up", in 9th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Florence (Italy), October-November, 1993, 48 (Abstract)

Milo, et al., "Copolymer-1 (COP-1) Regulates Class II MHC Expression and Cytokine Synthesis in the THP-1 Monocyte-Macrophage Cell Line" in The IBC Conference on Multiple Sclerosis, San Diego (USA), December 10, 1993 (Abstract)

EXAMINER

DATE CONSIDERED

3/8/03

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

App. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- Sela, "Polymeric Drugs as Immunomodulatory Vaccines Against Multiple Sclerosis", Makromol. Chem. Macromol. Symp., 1993, 70/71, 147-155
- Arnon, et al., "Immunospecific Drug Design - Prospects for Treatment of Autoimmune Disease", Therapeutic Immunol., 1994, 1, 65-70
- Bansil, et al., "Multiple Sclerosis: Pathogenesis and Treatment", Seminars in Neurol., June 1994, 14(2), 146-153
- The COP-1 Multicenter Clinical and Research Group Study, "COP-1 Multicenter Trial in Relapsing Remitting Multiple Sclerosis: 3 Year Follow Up", Abstracts of Symposia and Free Communication, Barcelona (Spain), June 25-29, 1994, 241 (Suppl. 1), 6
- Cotton, "Options for Multiple Sclerosis Therapy", J.A.M.A. Medical News & Perspectives, 1994, 272(18), 1393
- Dorling, et al., "Prospects for Xenografting", Curr. Opinions Immunol., 1994, 6, 765-769
- Fridkis-Hareli, et al., "Copolymer 1 Displaces MBP, PLP and MOG, but Can Not be Displaced by these Antigens from the MHC Class II Binding Site", Department of Chemical Immunology, The Weizmann Institute of Science, 1994
- Fridkis-Hareli, et al., "Direct Binding of Myelin Basic Protein and Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells - Specificity and Promiscuity", Proc. Natl. Acad. Sci. USA, 1994, 91, 4872-4876
- Fridkis-Hareli, et al., "Specific and Promiscuous Binding of Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", Israeli Biochem. Soc., 1994, 21-22 (Abstract)
- Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells" in Neurochem Mtg., August 14-19, 1994
- Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen- Presenting Cells", J. Neurochem., 1994, 63(Suppl. I), 561
- Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein do not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", Department of Chemical Immunology, The Weizmann Institute of Science, Rehovot, Israel, 1994

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form FTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Pat. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells", Cell. Immunol., 1995, 163, 229-236

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Undergo Processing Prior to the Binding to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells", Israeli Immunol. Soc., May 3-4, 1994 (Abstract)

Jacobs, et al., "Advances in Specific Therapy for Multiple Sclerosis", Neurol., 1994, 7, 250-254

Johnson, "Experimental Therapy of Relapsing-Remitting Multiple Sclerosis with Copolymer-1", Ann. Neurol., 1994, 36(Suppl.), 115-117

Kott, et al., "COP-1 Increases Suppressor Cells Number in Multiple Sclerosis", Israel Neurological Assoc., December 19-20, 1994, Herzliya (Israel), 17

Mengle-Gaw, "The Major Histocompatibility Complex (MHC)", in Encycl. Molecular Bio. (Oxford Blackwell Science Ltd, 1994) 602-606

Milo, et al., "Additive Effects of COP-1 and IFN-Beta on Immune Responses to Myelin Basic Protein", Neurol., 1994, 44(Suppl. 2), A212

Milo et al., "Additive Effect of Copolymer-1 and Interferon-B on the Immune Response to Myelin Basic Protein", Assaf Harofeh Medical Center, Sackler School of Medicine, Tel-Aviv University of Maryland School of Medicine, 1994, 22

Milo, et al., "Copolymer-1 and Interferon- β Additively Suppress the Immune Response to Myelin Basic Protein by Inhibiting Antigen Presentation", J. Neuroimmunol., 1994, 54, 183 (Abstract)

Nightingale, et al., "Access to Investigational Drugs for Treatment Purposes", Am. Family Physician, 1994, 50(4), 845-847

Tisch et al., "Antigen-specific immunotherapy: Is it a Real Possibility to Combat T-Cell-Mediated autoimmunity?" Proc. Natl. Acad. Sci. U.S.A., 1994, 91, 437-438

Schlegel, et al., "Prevention of Graft-Versus-Host Disease by Peptides Binding to Class II Major Histocompatibility Complex Molecules", Blood, 1994, 84(8), 2802-2810

Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", Ann. Neurol., 1994, 36, 114-115

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

App. Docket No.

60807-A-PCT-US

Serial No.

09/816,989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Alexander Gad et al.

Filing Date

March 23, 2001

Group Art Unit

1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Teitelbaum, et al., "Immunological Parameters in a Multicenter Clinical Trial of COPI in Multiple Sclerosis (MS): A 2-year Follow-up", Neurol., 1994, 44 (Suppl. 2), A358

Milo, et al., "Additive Effects of Copolymer-1 and Interferon β -1b on the Immune Response to Myelin Basic Protein", J. Neuroimmunol., 1995, 61, 185-193

O'Connor, et al., "Powders" in The Science and Practice of Pharmacy, Remington, 1995, 2, 1598-1614

Porter, "Coating of Pharmaceutical Dosage Forms," in The Science and Practice of Pharmacy, Remington, 1995, 2, 1650-1659

Reilly, Jr., W.J., "Pharmaceutical Necessities" in The Science and Practice of Pharmacy, Remington 1995, 2, 1380-1416

Schlegel, et al., "Inhibition of Allorecognition and Prevention of Graft-vs-host Disease (GVHD) by GLAT, a Synthetic Polymer with Promiscuous Binding to Murine and Human MHC Class II Molecules", in Am. Soc. Hematology, 37th Annual Meeting, Seattle, WA (USA), December 1-5, 1995, 224a (Abstract)

Ben-Nun, et al., "The Autoimmune Reactivity to Myelin Oligodendrocyte Glycoprotein (MOG) in Multiple Sclerosis is Potentially Pathogenic: Effect of Copolymer 1 on MOG-induced Disease", J. Neurol., 1996, 243 (Suppl. 1), S14-S22

Johnson, Management of Relapsing/Remitting Multiple Sclerosis with Copolymer 1 (Copaxone)", Chemical Abstracts, 1996, 125, 291993b

Sykes, "Immunobiology of Transplantation", Faseb J., 1996, 10, 721-730

Teitelbaum, et al., "Copolymer 1 Inhibits Chronic Relapsing Experimental Allergic Encephalomyelitis Induced by Proteolipid Protein (PLP) Peptides in Mice and Interferes with PLP-specific T Cell Responses", J. Neuroimmunol., 1996, 64, 209-217

Aharoni, et al., "Studies on the Mechanism and Specificity of the Effect of the Synthetic Random Copolymer GLAT on Graft-versus-Host Disease", Immunol. Letters, 1997, 58, 79-87

Puri et al., "Modulation of the Immune Response in Multiple Sclerosis", J. Immunol., 1997, 158, 2471-2476

Parcic et al., "Copolymer 1 (Copaxone) from an Idea to a Drug for Treatment of Multiple Sclerosis" Database HCAPLUS on STN, Israel: AN 1997:333270. Kim, Handasa Kim, 1997, 281 (14), 16-18 (Abstract)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

**U.S. Department of Commerce
Patent and Trademark Office**

Atty. Docket No.
60807-A-PCT-US

Serial No.
09/816,989

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants
Alexander Gad et al.

Filing Date
March 23, 2001

Group Art Unit
1644

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

Teitelbaum, et al., "Copolymer 1 from the Laboratory to FDA", Israel J. Med. Sci., 1997, 33, 280-284

Fridkis-Hareli, et al., "Promiscuous Binding of Synthetic Copolymer 1 to Purified HLA-DR Molecules", J. Immunol., 1998, 160, 4386-4397

Fridkis-Hareli, et al., "Synthetic Amino Acid Copolymers that Bind to HLA-DR Proteins and Inhibit Type II Collagen-Reactive T Cell Clones", Proc. Natl. Acad. Sci., 1998, 95, 12528-12531

Durelli, "Immunotherapeutics of Multiple Sclerosis", Istituto di Clinica delle Malattie del Sistema Nervoso Università di Torino, 467-475

EXAMINER

DATE CONSIDERED

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Atty. Dock [REDACTED]
60807-A-PCT-US

Serial No.
09/816.989

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants
Alexander Gad and Dora Lis

Filing Date
March 23, 2001

Group Art Unit
1644

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

[illegible]

EXAMINER

DATE CONSIDERED

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.